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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,146	04/24/2001	Harlan W. Waksal	11245/46604	5311

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EXAMINER
HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
1642	6

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,146	WAKSAL, HARLAN W.	
	Examin r	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 36-127 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 36-127 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restrictions

1. Prior to setting forth this restriction requirement, it is noted that claim 100 seems to contain a typographical error, and should be dependent from claim 99 and has been treated as such by the examiner.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 36-52 in part, 53-58, 73-76 in part, and 126-127, drawn to a method of treating a tumor by administering an EGFR antagonist antibody and a chemotherapeutic agent, classified in class 424, subclass 155.1 and class 514, subclass 1.

II. Claims 36-52 in part, 59-72, and 73-76 in part, drawn to a method of treating a tumor by administering an EGFR antagonist small molecule and a chemotherapeutic agent, classified in class 514, subclass 1.

III. Claims 77-80 in part and 122-125 in part, drawn to a method of treating a tumor by administering an EGFR antagonist antibody, a chemotherapeutic agent, and radiation, classified in class 424, subclasses 1.11 and 155.1, and class 514 subclass 1.

IV. Claims 77-80 in part and 122-125 in part, drawn to a method of treating a tumor by administering an EGFR antagonist small molecule, a chemotherapeutic agent, and radiation, classified in class 424, subclass 1.11, and class 514, subclass 1.

V. Claims 81-97 in part, 98-103, and 118-121, drawn to a method of treating a tumor by administering an EGFR antagonist antibody and radiation, classified in class 424, subclasses 1.11 and 155.1.

VI. Claims 81-97 in part and 104-117, drawn to a method of treating a tumor by administering an EGFR antagonist small molecule and radiation, classified in class 424, subclass 1.11 and class 514, subclass 1.

The inventions are distinct, each from the other, for the following reasons:

3. These methods are all distinct. They utilize different combinations of a broad range of therapeutic agents, employ different method steps, vary timing of administration and dosages, and treat a broad range of diseases. The method of Group I requires coadministration of an EGFR antagonist antibody and a chemotherapeutic agent. The method of Group II requires coadministration of an EGFR antagonist small molecule and a chemotherapeutic agent. The method of Group IIII requires coadministration of an EGFR antagonist antibody and a chemotherapeutic agent and radiation. The method of Group IV requires coadministration of an EGFR antagonist small molecule and a chemotherapeutic agent and radiation. The method of Group V requires coadministration of an EGFR antagonist antibody and radiation. The method of Group VI requires coadministration of an EGFR antagonist small molecule and radiation.

4. Antibody antagonists, small molecules, chemotherapeutic agents, and radiation agents are all distinct for each other. Each has a different structure, and a different mode of efficacy in treatment. Further, different combinations of these agents would produce different treatment results. In some cases, combinations of antibody antagonists, small molecules, chemotherapeutic agents, and/or radiation can produce additive or synergistic treatment results. In other cases,

antibody antagonists, small molecules, chemotherapeutic agents, and/or radiation can antagonize each other in treatment, and thus produce decreased or absent treatment efficacy. This varies by the nature of the disorder being treated, the nature of the antibody antagonists, small molecules, chemotherapeutic agents, and/or radiation being administered, and so forth. Thus combinations of such require distinct grounds of search and consideration.

5. Further, because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

A. If any of Groups I-VI are elected, applicant must further elect a species of cancer which is treated from those listed in claim 38.

These cancers and methods of treating such are distinct. Each cancer is cause by a different series of events, carries a different prognosis, and mandates a different treatment protocol, and thus require different grounds of search and consideration.

B. If any of Groups I-IV are elected, applicant must further elect a species of chemotherapeutic agent from those listed in claim 73.

These chemotherapeutic agents all possess different structures, act by different modes of action, require different treatment protocols, and have different efficacies, and thus require different grounds of search and consideration.

C. If any of Groups II, IV, or VI are elected, applicant must further elect a species of small molecule from those listed in claims 60-72. Applicant must elect a specific structure (not a generic category of structures) which can be searched.

These small molecules encompass a broad range of compounds which possess completely different structures, have different chemical properties and activities, require different treatment protocols, and have different efficacies, and thus require different grounds of search and consideration.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

AlH

Anne L. Holleran
Patent Examiner
July 1, 2002

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